K043104

FEB 2 4 2005

510(k) Summary
Kodak Orthodontic and OMS Imaging 8.0 software

1. Company Identification

Practiceworks, LLC, a subsidiary of Eastman Kodak Company
1765 The Exchange
Atlanta, GA 30339
Establishment Registration: Pending
Owner/Operator Registration: 1315356

2. Contact Person

Dan Hoefer
Manager, Regulatory Affairs
Kodak Dental Systems

3. Device Name

Commercial name: *Kodak Orthodontic Imaging 8.0, Kodak OMS Imaging 8.0*
Common name: Orthodontic and Oral Surgery Imaging Software
Classification name: System, Image Processing, Radiological

4. Device Classification

Class: II
Product Code: LLZ

5. Intended Use

Kodak Orthodontic and OMS Imaging 8.0 software is intended for use by orthodontists, oral surgeons and their clinical staffs in storing and organizing images, including digital photographs, x-rays, electronic models, and others. The system includes the capability to trace a cephalometric x-ray, analyze the measurements taken and make growth or surgical predictions.

6. Device Description

Kodak Orthodontic and OMS Imaging 8.0 software is designed for installation on an off-the-shelf PC running Microsoft Windows in a peer-to-peer network. Identical software is to be supplied to both orthodontic (commercial name: Orthodontic Imaging 8.0) and oral surgery (commercial name: OMS Imaging 8.0) markets.

The software consists of patient management software for orthodontic, and oral surgery practices. It provides the ability to connect satellite offices and will be marketed as a base system, with additional modules offered as options. The base system will include the storage, annotation and printing of images. The optional analysis module will allow the user to trace the cephalometric x-rays using standard analyses. The optional planner module will allow the user to simulate orthodontic or surgical treatment.

When the system is used with the TrophyPan or TrophyPan C panoramic and cephalometric x-ray systems (K023346, K033690, now marketed as Kodak 8000 and 8000C) the practitioner can acquire radiographic images of the dentomaxillofacial region, visualize anatomical structures through the use of a computer display and store the information electronically in a clinical software program that enables dental offices to keep records of hard and softcopy charts, treatment plans, clinical notes, and clinical exam data. The software does not natively control any x-ray device, but instead provides the user an interface by which he may access the control panels available with the Kodak 8000/8000C x-ray systems.

Kodak Orthodontic and OMS Imaging 8.0 software includes programming that enables the user to retrieve an electronic copy of an x-ray image from other imaging systems.

The imaging software can be integrated with Kodak practice management system software or used as a stand-alone product.

7. Substantial Equivalence

Kodak Orthodontic and OMS Imaging 8.0 is substantially equivalent to Chairside (K982422, EagleSoft) and DentalEye (K012439, Radco Data AB).

- Each device is indicated for use in dental or dental sub-specialty diagnostic image storage, editing, communication, manipulation and viewing.
- The technological characteristics and principles of operation are equivalent, as each device is software that operates on a Windows-based PC platform.
- The intended users of each device are the same or similar.
- The devices are equivalent in terms of energy used or delivered, materials, biocompatibility, standards, and other applicable characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Daniel Hoefer
Manager, Regulatory Affairs
Kodak Dental System
Practice Works, Inc.
1765 The Exchange
ATLANTA GA 30339

Re: K043104
Trade/Device Name: Kodak Orthodontic Imaging and OMS Imaging Version 8.0
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: January 21, 2005
Received: January 24, 2005

Dear Mr. Hoefer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K043104

Indications for Use

510(k) Number (if known):

Kodak OrthoImaging 8.0 software is indicated for use by orthodontists and their clinical staff in storing and organizing images, including digital photographs and x-rays. The device includes the capability to trace a digital cephalometric radiograph, analyze the measurements taken and make growth or surgical predictions.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter
(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043104